The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

December 4, 2023

The Honorable Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Janet L. Yellen
Secretary of Department of the Treasury
U.S. Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

The Honorable Julie Su
Acting Secretary of Department of Labor
U.S. Department of Labor
200 Constitution Ave NW
Washington, DC 20210

RE: Request for Information; Coverage of Over-the-Counter Preventive Services

Dear Secretary Becerra, Secretary Yellen, Acting Secretary Su,

The American College of Obstetricians and Gynecologists (ACOG) represents more than 62,000 physicians and partners dedicated to advancing women's health and the health of individuals seeking obstetric and gynecologic care. ACOG welcomes the opportunity to comment on the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury (collectively, the Departments) request for information on the Coverage of Over-the-Counter (OTC) Preventive Services. As physicians dedicated to providing quality care to those seeking obstetric and gynecologic care, ACOG continues to support the goals of the Patient Protection and Affordable Care Act (ACA) to expand access to continuous and meaningful health insurance coverage and cost-free contraceptives. ACOG appreciates the Departments soliciting information on the best practices for this coverage, as well as other preventive services such as breastfeeding equipment and supplies.

Background

Section 2713 of the Public Health Service (PHS) Act, as passed by the ACA, requires all non-grandfathered individual and group health plans to offer coverage of women's preventive services with no cost-sharing. Under the ACA, the uninsured rate among women ages 18-64 decreased by nearly half, from 19.3 percent to 10.8 percent, and the uninsured rate for children and adolescents reached a historic low of 4.8 percent.[i,ii] Over 62 million women with private insurance have since gained access to vital preventive health care services, including breast and cervical cancer screening, breastfeeding services and

supplies, and contraception and contraceptive counseling.[iii] Contraception and contraceptive counseling are cornerstones of effective prevention in women's health. Section 2713 of the PHS Act represents an agreement among policymakers and physicians that preventive care is critically important and helps avoid the use of costlier specialty care. We strongly believe that those of reproductive age should continue to have access to affordable birth control and that insurance should cover all U.S. Food and Drug Administration (FDA)-approved contraceptive methods with no cost-sharing as an integral part of preventive care services.

The benefits of birth control have been well documented. The Centers for Disease Control and Prevention (CDC) named birth control one of the top ten public health achievements of the past century.[iv] Birth control is also widely credited for contributing to women's societal, educational, and economic gains. Beyond the well-established evidence that contraceptives are effective in the prevention of unintended pregnancy, the non-contraceptive health benefits of contraception recognized in evidence include decreased bleeding and pain with menstrual periods, decreased premenstrual syndrome and premenstrual dysphoric disorder, and reduced risk of gynecologic disorders, including, myoma, pelvic inflammatory disease, and a decreased risk of endometrial and ovarian cancer.[v,vi] The provision of contraception in the ACA was designed to promote preventive health care, reduce future medical costs, and improve the health of women, adolescents, and families.

The Dobbs decision has made accessing abortion incredibly difficult, if not impossible, for millions of people across the nation. The Departments have stated in the past that the abortion access crisis caused by Dobbs has "placed a heightened importance on access to contraceptive services." It is vital to note, however, that improved access to contraception does not, and could not ever, replace access to abortion. Both services are essential in the full spectrum of reproductive health care, to which everyone deserves access in their own community.

The nation's experts predict that the current U.S. maternal mortality crisis will only worsen now that there is no federal protection for abortion care.[vii] Even now, the U.S. has the highest maternal mortality and morbidity rate of all developed nations, with a rate of 32.9 deaths per 100,000 live births in 2021.[viii] Further, Black and American Indian/Alaska Native women are roughly three times more likely to die from pregnancy-related causes than white women.[ix] Additionally, throughout the COVID-19 pandemic, overall maternal health outcomes worsened and gaps in disparities widened. Improving access to over-the-counter breastfeeding supplies may help improve overall maternal health outcomes as breastfeeding is associated with a decrease in a woman's risk of breast cancer, ovarian cancer, diabetes mellitus, and hypertensive heart disease.[x]

Since 2012, ACOG has supported over-the-counter access to oral contraception.[xi,xii] Access to contraception, especially methods that are user-dependent (versus those that are reliant on a partner, such as with condoms), is even more important today when reproductive access and choices are limited for many Americans. Based on the robust body of evidence supporting the safety and efficacy of hormonal contraception, ACOG supports the switch from prescription to over-the-counter access to progestin-only oral contraceptive pills (POPs) without age restrictions.

Access to and Utilization of OTC Products

Contraception

Contraception, including OTC contraception, is a critical preventive health service, essential in individuals' achievement of their health, social, and financial goals.[xiii] The ACA has already greatly advanced access to contraception, among other preventive services, partially rectifying existing disparities.[xiv,xv,xvi] However, many Americans continue to face multiple and persistent barriers to

contraception more than ten years after the implementation of the ACA. These barriers significantly impact people of color and Indigenous people, young people, immigrants, LGBTQ+ communities, those working to make ends meet, and people with disabilities.[xvii] A national survey of people who identify as Black, Indigenous, and people of color found that nearly half experienced at least one challenge to accessing contraception in the last year.[xviii]

Nearly all women utilize some method of contraception during their reproductive lives.[xix] Data from the 2017–2019 National Survey of Family Growth show that approximately 65 percent of adolescent and adult women aged 15–49 years currently were using contraception; oral contraceptive pills were one of the most frequently-used methods (14 percent).[xx] Data clearly show that patients benefit from contraception and are interested in its use; and yet, individuals regularly face obstacles that are not based on medical or scientific fact. As noted by the Centers for Disease Control and Prevention's (CDC) evidence-based review of contraceptive methods, the *U.S. Selected Practice Recommendations for Contraceptive Use*, for those in good general health, no examinations or tests are needed before the initiation of POPs. Additionally, individuals with hypertension, diabetes, anemia, thrombogenic mutations, cervical intraepithelial neoplasia, cervical cancer, sexually transmitted infections, including human immunodeficiency virus (HIV), can safely use progestin-only pills.[xxi] Barriers, such as clinicians requiring a pelvic or clinical breast examination or cervical cancer screening prior to prescription, are not rooted in science. Also, pharmacist refusals to fill contraceptive prescriptions and pharmacies that refuse to stock contraceptives are considerable barriers. As noted by the National Women's Law Center, pharmacy refusals to dispense contraception have been reported in 26 states.[xxii] Although some individuals have access to an alternative pharmacy, those who live in areas where pharmacies and pharmacists are limited, such as rural areas, may find insurmountable obstacles to obtaining prescribed contraception.[xxiii] Other commonly reported obstacles to accessing contraception include cost barriers or lack of insurance; challenges obtaining an appointment or getting to a clinic; not having a regular clinician; and difficulty accessing a pharmacy.[xxiv] Indeed, research shows that interest in OTC contraceptives, particularly birth control pills, increases if they are covered by insurance.[xxv] [xxvi] Timely access to refills is especially essential with the use of POPs which require consistent use at the same time each day.

Breastfeeding Supplies

Breastfeeding initiation rates in the United States are increasing, and many women are aware of the maternal and infant health benefits of breastfeeding. More than 83% of infants are breastfed at birth, and women are choosing to breastfeed longer.[xxvii] ACOG recommends exclusive breastfeeding for the first 6 months of life, with continued breastfeeding while complementary foods are introduced during the infant's first year of life, or longer, as mutually desired by the woman and her infant.[xxviii] Problems may arise that can keep women from achieving their breastfeeding goals, and only 25.4 percent of women are breastfeeding exclusively at 6 months.[xxix] In a longitudinal cohort study of women in the United States, 45 percent of women reported early, undesired weaning, and approximately two-thirds of women weaned earlier than they had intended.[xxx] Causes of early weaning can vary from physical reasons to societal factors.

The ACA requires most insurance plans to cover the cost of a breast pump and breastfeeding counseling without cost sharing. Current guidelines recommend "comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding."[xxxi] Additional guidance in 2023 states "breastfeeding equipment and supplies include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies.[xxxii] Access to double electric pumps should be a priority to optimize breastfeeding and should not be predicated on prior failure of a manual pump. Breastfeeding equipment may also include equipment and

supplies as clinically indicated to support [nursing parents and infants] with breastfeeding difficulties and those who need additional services." While less data have been collected about OTC access to breastfeeding supplies, research shows out of pocket costs to breastfeeding supplies are a barrier to individuals wishing to breastfeed. While insurance plans may be covering breastfeeding supplies with no out of pocket costs, administrative burdens, such as requiring a prescription, can still be a barrier to needed supplies and supports for patients.

Implementation Issues

Point of Sale Coverage
ACOG continues to believe that cost-sharing should be eliminated for patients to improve access to important services and procedures. Studies show that cost-sharing has unintended consequences such as unbearable financial burdens, negative effects on access to health care and health outcomes, and increased use of emergency rooms.[xxxiii] Small levels of cost-sharing in the range of $1 to $5 can significantly correlate to reduced use of services, especially medically necessary services.[xxxiv] These practices are often methods in which payers can restrict access to clinically appropriate care and should be reduced or removed entirely.

Despite the ACA's provisions regarding contraceptive coverage with no out-of-pocket costs, accessing health care can be difficult and expensive. For example, millions of women live in contraceptive deserts or are otherwise far from a trusted provider; financial factors like needing to arrange transportation, childcare, and time off work (often in the absence of paid sick days can make getting contraception from a provider prohibitively expensive).[xxxv, xxxvi] Additionally, a process which requires payment by the patient to later be reimbursed is not tenable and does not provide the economic benefits of contraception as intended by the ACA. Without direct payment for OTC contraception, existing disparities will persist.

Currently, the limitations of payers' claims processing systems create challenges for access in out-of-network pharmacies and retail settings, which poses a serious challenge to people who have limited resources or difficulty accessing pharmacies. As noted above, reimbursement-based processes of implementing coverage still place a cost burden on individuals. Solutions to extend OTC coverage to retail settings may include a coverage "debit" card similar to electronic benefits transfer cards used for other programs. Federal requirements for insurers to provide coverage of OTC contraceptives that includes point of sale payment to all pharmacies and retail settings, without cost-sharing and without a prescription would help close the gaps in disparities and inequities. **ACOG strongly urges the Departments to ensure point of sale coverage to consumers to ensure consumers face no financial barriers to care.**

Quantity Limitations
There is ample precedent for coverage of a 12-month supply of contraception. Currently, 25 states and the District of Columbia have required private insurance plans and/or Medicaid plans to cover an extended (usually 12-month) supply of contraceptives.[xxxvii] Moreover, the July 2022 tri-agency FAQ document encourages (but does not require) plans to cover a 12-month supply, based on research findings that "dispensing a 12-month supply at one time can increase the rate at which use of contraceptives continues, decrease the likelihood of unintended pregnancy, and result in cost savings."[xxxviii]

While there are not established standards for what constitutes a 12-month supply for some OTC methods (e.g., condoms and emergency contraceptive pills), health plans should be prohibited from setting unreasonable quantity limits that would compromise individuals' ability to use these methods effectively. Plans should cover OTC products in all quantities that are packaged for retail sale (e.g., not limit coverage of condoms to boxes of 10 or 12, when they are also sold in larger box sizes). **ACOG strongly**

recommends federal rules should require health plans to cover a 12-month supply of contraceptives (whether OTC or prescription) at one time.

In addition, health plans should be barred from placing limits on a patient's ability to switch contraceptive methods. Often a person must change methods due to side effects, a change in life circumstances, or find the method that works best for them. They should be able to do so without obstacles. For example, receiving a 12-month supply of oral contraceptives should not prevent a patient from switching to an IUD six months later. Similarly, health plans should be required to offer additional coverage in cases when a consumer's supply of contraceptives is lost or damaged. These protections would help ensure that health plans do not undermine enrollees' health in the name of preventing fraud and abuse.

Location/network requirements
There should be broad coverage of OTC products across locations. At minimum, this must include anywhere consumers can use their prescription benefit, including a drugstore pharmacy counter or an insurer's mail-order pharmacy service. Additionally, the federal government should work with health plans and retailers to develop ways for consumers to obtain OTC contraceptives with no copay at any retailers—for example, by using a plan-issued debit card or an electronic coupon via a QR code.

In order for consumers to have a full range of convenient options, plans should also be required to cover the full cost of OTC contraceptives when an enrollee buys the product up front without their insurance, at any location, and then submits the receipt for after-the-fact reimbursement. However, after-the-fact reimbursement must never be used by health plans as the preferred option—rather, they should ensure true point-of-sale coverage. **ACOG recommends federal rules require health plans to cover OTC products in as many locations as possible—ideally, anywhere that OTC drugs and devices are sold, including coverage for telemedicine and mail-order options.**

Services provided by obstetrician-gynecologists range throughout the lifespan and are critical for individuals seeking care. Applying network adequacy to all plans is a key piece in ensuring those seeking obstetrical and gynecological care have access to the providers and care they need. Through the Notice of Benefit and Payment Paraments (NBPP) rule making process, the Departments can set network adequacy standards for qualified health plans (QHP) and threshold standards for Essential Community Providers (ECP). **ACOG recommends the Departments include retailers providing OTC coverage of preventive services to network adequacy standards through the NBPP rule making process to ensure broad access to these services, including contraception.**

Uniform Guidance
As of 2023, eight states have passed laws requiring insurance coverage of OTC contraception. In states where coverage for OTC contraception is provided without a prescription, research shows that billing protocols for OTC contraception vary widely by health insurance plan and within state Medicaid programs, leading to confusion for pharmacists.[xxxix] And while state actions to increase access to OTC contraception without cost-sharing and without a prescription can be meaningful for people with private insurance, the reach of these actions is limited because the majority of those with private health insurance are enrolled in self-funded employer plans, which are not subject to state insurance requirements.[xl]
ACOG urges the Departments to issue guidance clarifying that the preventive services provision requires that coverage of OTC preventive products, including contraception and breastfeeding supplies, without a prescription be comprehensive and seamless, no matter how a consumer acquires the product.

A national, uniform approach to processing claims for OTC products is critical. Pharmacists and pharmacies report that claims processing often varies between plans and product, and that as a result,

there is confusion about how to process OTC claims. Due to market segmentation, each individual state has limited ability to effect the systemic changes needed to process insurance claims for OTC products. A national requirement for coverage creates the imperative for stakeholders to come to the table and develop a uniform approach to processing OTC coverage claims. **ACOG recommends federal regulations create a uniform process for all plans to process OTC product claims.**

Considerations from the States

To reduce access barriers to OTC contraception while also avoiding cost sharing, six states (CA, MD, NJ, NM, NY, and WA) have laws or regulations requiring state-regulated private health insurance plans (individual, small group, and large group markets) to cover, without cost sharing, at least some methods of OTC contraception without a prescription.[xli] With the exception of New York, which applies only to emergency contraception, the language of these laws is broad enough to encompass an OTC daily oral contraceptive without a change in policy. Illinois and Oregon require private health plans to cover OTC contraception; however, while the laws do not state that a prescription is required in order for it to be covered by insurance, the laws also do not explicitly stipulate that plans must cover them without a prescription. Delaware and Massachusetts require private plans to cover OTC emergency contraception with a prescription or pursuant to a standing order or protocol. While federal law applies to all plans, state law applies to only individual plans and fully-insured group plans. Therefore, many people who live in states that require coverage of OTC contraception without a prescription may not have this benefit if they are enrolled in a self-funded employer-sponsored health plan (65 percent of covered workers nationally). **ACOG recommends the Departments look to states with OTC coverage and use lessons learned to ensure a smooth roll out of the national OTC coverage benefit.**

While some states have taken action to expand access, others have taken legislative action that sets precedents to limit availability. Idaho's No Public Funds for Abortion Act, which passed in 2021, prohibits state-funded student health centers from counseling patients on abortion and bars them from distributing emergency contraception like Plan B.[xlii] Iowa's Crime Victim Compensation Program no longer provides Plan B for survivors of sexual assault.[xliii] The Texas Medicaid-funded family planning program excludes emergency contraceptives.[xliv] Of significant concern, 5th U.S. Circuit Court of Appeals upheld U.S. District Judge Matthew Kacsmaryk's ruling that Title X, a federal program that provides free, confidential contraception to anyone, regardless of age, income or immigration status, violates parents' rights and state and federal law.[xlv] **ACOG strongly urges the Departments to develop federal regulations that protect OTC contraception and other OTC preventive services from state laws that attempt to restrict access to these critical products.**

Provider Impacts

Many of the issues identified in implementation, such as prior authorization and prescription requirements, impact patients and providers. ACOG strongly believes that policies which add burden to physicians ultimately impact patient access. For example, utilization management mechanisms such as prior authorization are typically unnecessary and can be barriers to accessing critical care and services. In addition to the burden physicians and their practices experience in regard to prior authorization, patient safety is also often at risk. A 2021 survey conducted by the American Medical Association (AMA) showed that 93 percent of physicians report care delays for services and treatments requiring prior authorization and 34 percent of physicians surveyed reported the prior authorization requirements have led to a serious adverse event in a patient's care.[xlvi] **ACOG urges the Departments to ensure no utilization management techniques, like prior authorization, are allowed in OTC coverage policies as it creates an unnecessary barrier to patients and providers.**

The current standards around OTC coverage pose a burden for both patients and providers working in the most underserved communities. This is only exacerbated by the exodus of physicians from states with

abortion bans. There are increased demands on physicians via appointments, phone calls, and electronic messaging from patients to write prescriptions without an appointment. In many of these circumstances, the physician isn't compensated for their labor and time, adding to burnout as these physicians try to keep up with patient needs. Allowing patients to seek OTC products without a prescription has the opportunity to increase the capacity for physicians to provide other services and take on new patients. Additionally, OTC products exist because the FDA has determined that the products have minimal risks associated with them, and patients are able to discern for themselves usage. Given these facts, **ACOG supports OTC coverage of these products and services to help support physicians and prevent health issues or patients concerns without relying on a physician visit or prescription requirement.**

Health Equity Across Federal Programs

People from racially and ethnically marginalized communities are more likely to face barriers to accessing reproductive health care and are less likely to use hormonal contraception, in part, due to these obstacles. Data also support that uninsured people and those for whom English is not their first language face even more difficulty accessing prescription contraception.[xlvii] While preferences for contraceptive method and attitudes toward pregnancy may explain some differences in contraceptive use by Black, Hispanic, and White individuals, clinician-related factors also contribute to disparities in reproductive health care. Survey data show that Black individuals are more likely than White people to be pressured to initiate contraception by a clinician and that Hispanic women are more likely to be counseled about permanent sterilization.[xlviii] While efforts to dismantle racism in health care and reform clinician bias are essential, additional avenues for individuals to access contraception on their own terms provides equity in family planning. **Ensuring OTC coverage of preventive services without a prescription is a small step the Departments can take to address growing health disparities and inequities within the health care system.**

Adolescents and young adults especially may face substantial barriers to accessing desired contraception. In a 2022 survey from Advocates for Youth, 88 percent of the respondents reported difficulty accessing birth control.[xlix] Many young people experience challenges scheduling, traveling to, and attending an appointment with a clinician to get a prescription for contraception. This can lead to delays starting birth control or some may never access contraception. Adolescents also have unique privacy needs that are often compromised by documents from their parents' insurance coverage.[l] Based on these unique challenges and the safety and efficacy of oral contraception, ACOG supports OTC contraception availability without age restrictions. **ACOG recommends the Departments include provisions in rule-making to allow for privacy in explanation of benefit statements for OTC contraceptive products.**

The Departments must take steps to ensure an equitable roll out of OTC coverage across all federal programs. Specifically, to help close the gap on health inequities and disparities for reproductive care, the Centers for Medicare & Medicaid Services (CMS) and the Center for Medicaid and CHIP Services (CMCS) will need to develop national coverage policies to ensure OTC contraceptives are covered without cost-sharing and without a prescription for beneficiaries of Medicare and Medicaid that are of reproductive age.

Medicare, originally designed as a hospital benefit for older Americans, now include approximately 1.7 million people ages 18 through 44.[li] HHS, along with CMS, should take this opportunity to update coverage policies to align with ACA recommendations and also allow for coverage of OTC contraception.

Within Medicaid, contraceptives are covered under three different benefit categories, the prescription drug benefit, the family planning benefit, and the essential health benefits preventive services benefit, and federal action is needed to ensure a smooth roll out OTC coverage of contraception. States can cover OTC contraceptive drugs under the prescription drug benefit, which would allow the state to receive drug

rebates from the manufacturer but would require the beneficiary to have a prescription. Alternatively, states can cover OTC contraceptive drugs and devices under the family planning benefit without a prescription, but any OTC product covered without a prescription, under either the family planning benefit or the essential health benefit for preventive services, would be ineligible for a rebate, making it more expensive for Medicaid programs. Additionally, with the ACA Medicaid Expansion group and those only eligible for family planning services, multiple actions are needed. For ACA Medicaid Expansion beneficiaries, current ACA guidance says coverage must include a list of specific OTC contraceptives, but a prescription may be required by the Medicaid plan. For all other Medicaid beneficiaries, current federal law and regulations allow but do not require states to cover OTC contraceptives. **ACOG recommends CMS issue a federal standing order for OTC contraceptives applying to all Medicaid beneficiaries nationwide to remove policy barriers to OTC coverage for state Medicaid programs. Additionally, ACOG recommends CMS issue guidance to states outlining OTC coverage requirements for Medicaid beneficiaries, including the expansion group, provide technical assistance to states, and promote the coverage availability to beneficiaries.**

Enforcement and Oversight

ACOG recommends that the Departments provide clear information about the ACA's requirements and specifically about coverage of OTC preventive products to all impacted groups including private health plans, Medicaid managed care plans, pharmacy benefit managers, state insurance regulators, state Medicaid agencies, pharmacies, retailers, community-based organizations, providers, and consumers**.** Similarly, the Departments will need to disseminate instructions for implementation by programs and providers and access by patients. Moreover**, ACOG strongly recommends that the Departments partner to monitor compliance with the revised requirements, impose appropriate corrective actions and penalties for plans that fail to do so, and work with state regulators to coordinate oversight and enforcement across the entire health coverage marketplace.**

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Thank you for the opportunity to comment on the request for information on the Coverage of Over-the-Counter (OTC) Preventive Services. As articulated above, ACOG believes access to OTC preventive services without a prescription is critical to the health and well-being of our patients. We urge the Departments to develop federal regulations that create robust coverage of OTC preventive services and provide support and guidance for implementation. Should you have any questions, please contact Taylor Platt, Manager, Health Policy, at tplatt@acog.org or 202-314-2359.

Sincerely,

Lisa Satterfield, MS, MPH, CAE, CPH
Senior Director, Health Economics & Practice Management

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